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genedrive plc
("genedrive" or the "Company")

NHS implementation guide published for CYP2C19 genotype testing

genedrive plc (AIM: GDR), the point of care pharmacogenetic testing company, notes the publication of the "NHS implementation guide for CYP2C19 genotype testing to guide Clopidogrel use after ischaemic stroke ("IS") or transient ischaemic attack ("TIA")" to support prescribing decisions in stroke.

Following the National Institute for Health and Care Excellence ("NICE") recommendation for CYP2C19 genotyping in TIA and IS including the Genedrive® CYP2C19 ID Kit as the preferred rapid testing platform, and a national pilot implementing both laboratory and "rapid testing" approaches, the implementation guide encourages stroke services to use the guide to plan how CYP2C19 genotype testing could be integrated locally. Interim presentation of the pilot results highlighted that the vast majority of stroke patients had moved further down the care pathway by the time results were available from laboratory testing (which takes several days to weeks), whereas actionable results were available from rapid testing within just over one hour.

The guide notes that;

- *Patients at hyperacute stroke units typically have a short length of stay, which may be more suitable for rapid testing.*
- *In the context of TIA and non-disabling stroke, clopidogrel is typically started immediately. Turnaround time of laboratory testing means patients may require an additional appointment to change their prescription. This group of patients may be receiving less effective secondary prevention for the days between the test and until an alternative medicine is started.*
- *Rapid testing may reduce the need for follow-up appointments or additional communication to other services to action a prescribing decision.*
- *Rapid testing devices can be housed within local pathology laboratories in addition to frontline clinical areas.*
- *Hyperacute stroke units, or centres with high volume TIA admissions may benefit from rapid testing.*
- *As Point-of-Care (rapid) testing provides real-time results, treatment decisions can be made immediately.*
- *Laboratory based testing is under review for national commissioning and if included in the NHS National Genomic Test Directory then the cost of the test (excluding logistics) will be funded centrally. Whereas funding for rapid testing must be met at trust or Integrated Care Board (ICB) level.*
- *Rapid testing devices from different providers may test for different genetic variants, therefore it is recommended to undertake a local equality impact assessment to understand the prevalence of variants across local diverse populations.*

Further details are available at:

https://www.nw-gmsa.nhs.uk/about-us/our-projects/genomic-networks-excellence/pharmacogenomics-and-medicines-optimisation-genomic-network-excellence/clopidogrel-pilot-project-cyp2c19-genetic-testing-stroke-and-tia-patients

Dr Gino Miele, CEO of genedrive plc, said: *"The publication of the NHS implementation guide for delivery of CYP2C19 genotype testing is well-overdue, having been expected earlier this year. Whilst light on detail, publication of it is welcome, confirming the value of rapid testing solutions to stroke patients, particularly in enabling more immediate prescribing decisions to TIA patients. As expected, laboratory-based testing funding is likely to fall within Genomic Test Directory commissioning, whereas rapid testing procurement is likely to be required to be met at trust and ICB level, where our focus has been predominantly placed commercially in recent months."*

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About genedrive plc (http://www.genedrive.com)

genedrive plc is a pharmacogenetic testing company developing and commercialising a low cost, rapid, versatile and simple to use point of need pharmacogenetic platform for the diagnosis of genetic variants. This helps clinicians to quickly access key genetic information that will aid them make the right choices over the right medicine or dosage to use for an effective treatment, particularly important in time-critical emergency care healthcare paradigms. Based in the UK, the Company is at the forefront of Point of Care pharmacogenetic testing in emergency healthcare. Pharmacogenetics informs on how your individual genetics impact a medicines ability to work for you. Therefore, by using pharmacogenetics, medicine choices can be personalised, made safer and more effective. The Company has launched its two flagship products, the Genedrive® MT-RNR1 ID Kit and the Genedrive® CYP2C19 ID Kit, both developed and validated in collaboration with NHS partners and deployed on its point of care thermocycler platform. Both tests are single-use disposable cartridges which are ambient temperature stable, circumventing the requirement for cold chain logistics. The Directors believe the Genedrive® MT-RNR1 ID Kit is a worlds-first and allows clinicians to make a decision on antibiotic use in neonatal intensive care units within 26 minutes, ensuring vital care is delivered, avoiding adverse effects potentially otherwise encountered and with no negative impact on the patient care pathway. Its CYP2C19 ID Kit which has no comparably positioned competitor currently allows clinicians to make a decision on the use of Clopidogrel in stroke patients in 70 minutes, ensuring that patients who are unlikely to benefit from or suffer adverse effects from Clopidogrel receive an alternative antiplatelet therapeutic in a timely manner, ultimately improving outcomes. Both tests have undergone review by the National Institute for Health and Care Clinical Excellence ("NICE") and have been recommended for use in the UK NHS. The Company has a clear commercial strategy focused on accelerating growth through maximising in-market sales, geographic and portfolio expansion and strategic M&A, and operates out of its facilities in Manchester.

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